Surprise District Court Ruling Invalidates Myriad Genetics' BRCA Patents, But Appeal is Pending

Bob Carlson, MHA, Senior Contributing Editor

On the afternoon of Monday, March 29, 2010, patent attorneys, patent holders, and venture capitalists with interests in patents on human genes sat up straight in their big black leather chairs.

What got their attention was the just-released opinion of Judge Robert W. Sweet, U.S. District Court for the Southern District of New York, *In Association for Molecular Pathology, et al v. United States Patent and Trademark Office, et al*.

Plaintiffs, represented by the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT), on May 12, 2009, challenged the legality of Myriad Genetics' patents on the human BRCA1 and BRCA2 genes.

Mutations in these genes confer an increased risk of breast and ovarian cancer. Myriad Genetics markets the BRACAnalysis test, which identifies these mutations by sequencing the BRCA1 and BRCA2 genes and comparing them with their "wild-type" counterparts.

How this suit is ultimately decided could affect huge swaths of diagnostics and therapeutics R&D — anything, really, having to do with human genes.

The question before the court, in Judge Sweet's words, was: Are isolated human genes and the comparison of their sequence patentable? In his 156-page opinion, Judge Sweet concluded that the answer is no.

SURPRISED AND DISMAYED

Most members of the patent bar were surprised and some were dismayed by this decision, the first time a court has ruled that patents on human genes are invalid. Patents on human genes are not a big deal, or at least they were not before this decision. After all, about 2,000 human genes have already been patented.

"I was surprised that a district court judge would decide that, not just these patents, but the whole line of isolated DNA sequence patents and their methods of use would not be patent eligible," says Michael R. Samardzija, PhD, counsel at Bracewell & Giuliani, LLP, in Houston. "I think it's contrary to the [U. S.] Court of Appeals for the Federal Circuit precedent."

One example of what Samardzija considers contrary to rulings by the appeals court (the very same court that will hear Myriad's appeal) is Judge Sweet's conclusion that genes are primarily information, such that "DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature."

"I understand a gene is information, but so is a small molecule that binds to a beta receptor and blocks it," argues Samardzija, who is knowledgeable in both molecular biology (his previous career) and life sciences patent law, which he has been practicing since 2001.

Another point of contention is whether the BRCA1 and BRCA2 genes are products of nature, an exception created by case law that would make them unpatentable subject matter. In Judge Sweet's opinion: "Because the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 U.S.C. § 101."

Samardzija disagrees.

"What is claimed here does not exist in nature," he retorts. "What is claimed is the isolated gene, and we do not have isolated genes in our bodies."

THE "METHOD CLAIM" WILD CARD

Finally, there's the "method claim," which refers to the polymerase chain reaction (PCR) technique Myriad uses to isolate the BRCA1 and BRCA2 genes in patient blood samples. The resulting gene sequences are then compared with the sequences of "wild-type" (i.e., "normal") BRCA1 and BRCA2 genes. PCR has been used in genetic research for almost three decades, and the mental act of comparing gene sequences falls under the "abstract ideas" exception. Judge Sweet concludes that, "Similarly, because the claimed comparisons of DNA sequences are abstract mental processes, they also constitute unpatentable subject matter under §101."

In an October 2008 en banc[1] decision in *Bilski v. Doll*, the U. S. Court of Appeals for the Federal Circuit ruled that a method for hedging against fluctuations in the cost of energy commodities is not patentable because it is too abstract. Specifically, the 9-3 majority decided that patentable business processes must involve "a machine" and result in a "transformation."

[1] En banc refers to the hearing of a legal case where all judges of a court will hear the case, rather than a panel of judges. For example, when all members of an appellate court hear an argument, they are sitting en banc.

The question before the Court, in Judge Sweet's words was: Are isolated human genes and the comparison of their sequence patentable? In his 156-page opinion, the Judge concluded that the answer is no.

That 2008 opinion actually contradicts a 1998 decision by the same court that business methods with a "useful, concrete and tangible result" are patentable. The United States Patent and Trademark Office had in the interim granted thousands of patents based on that 1998 decision.

The software, financial services, and biotechnology industries have been anxious for a definitive opinion on exactly what makes a business method patentable, and on June 1, 2009, the Supreme Court agreed to review *Bilski*. A decision is expected soon.

PUBLIC POLICY DECISION?

"Yes, I was surprised by the outcome, and I also was surprised that it was a summary judgment," says Thomas C. Meyers, counselor at law and chair of the life sciences Intellectual Property Practice Group at Brown Rudnick, LLP, in Boston.

Meyers, who does patent strategy and planning for biotechnology and pharmaceutical companies, explains that a summary judgment is appropriate when no material facts are in dispute.

"If Judge Sweet's decision is upheld, that would have wide-ranging implications on the industry," Meyers says, but adds, "What the Supreme Court says in *Bilski* may make this whole thing go away."

Like Samardzija, Meyers insists that an isolated, purified gene is not a product of nature. "That gene looks very different in that state than it does when it's in someone's body. You have to select which portions you want to take and strip it away from its histone proteins. It has to be processed in some way, and all that changes it."

Judge Sweet's opinion strikes Meyers as more of a public policy decision by a judge whose "public policy aspiration" took precedence over the application of the law.

"Wanting to make the BRCA genes widely available at low cost to the public, I mean, of course there's a benefit to that," Meyers clarifies. "But if you do that, have you disincentivized the folks who are going to spend the millions and sometimes hundreds of millions of dollars it takes to develop a diagnostic test or to get a drug approved by the FDA? The whole point of the patent system is that we will give you an exclusive right to your invention for a limited period of time. That promotes technology development and innovation. If you don't have that expectation of exclusivity, hey, if it were my money, I wouldn't invest it. Would you?"

A VERY LONG-STANDING RULE

"The notion that the judge's decision is social engineering or some sort of liberal bias or judicial activism is ludicrous," asserts Christopher Hansen, staff attorney with the ACLU and lead plaintiff attorney. "It has been a doctrine of the Supreme Court for over a hundred years that it is impermissible to patent products of nature or laws of nature. All the Judge did was apply that very long-standing rule of patent law to find that human genes are products of nature."

Hansen finds Sweet's opinion "a triumph of common sense" and argues that human genes, albeit isolated and purified, are unpatentable products of nature.

"The whole point of looking at the gene in its isolated form is to find out what the gene looks like inside the body," Hansen continues. "Therefore, almost by definition, if it's been transformed by the process of isolation, it becomes useless. The gene sequence is caused by nature, the gene mutations are caused by nature, and the significance of the mutations is caused by nature. No human being invented any of those things."

Hansen agrees that the Supreme Court's ruling in *Bilski* may affect the ultimate resolution of the method claim, but he does not believe that Judge Sweet's opinion necessarily invalidates all human gene patents.

"It certainly doesn't invalidate patents on genes that don't exist in nature, and it may or may not invalidate other gene patents, depending upon how they're drafted," he says.

Samardzija takes a similarly measured view. "I think it's going to cause some trouble for tests that look specifically at isolated DNA sequences. But personalized medicine has moved on from the patents that were granted to Myriad. Newer in vitro diagnostic patents look at many alleles, and, in my opinion, the judge did not rule that these multi-allele tests are patent-ineligible subject matter."

What happens next could pull the rug right out from under those big black leather chairs. A three-judge panel of the U. S. Appeals Court for the Federal Circuit typically hears these appeals. The court is expected hear Myriad's appeal by fall or winter of 2010.

Bob Carlson, MHA, writes exclusively about health care. He lives near Zionsville, Ind.